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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/421,971 10/20/99 GAGE

F SALK2350

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EXAMINER

MURPHY, J

ART UNIT

PAPER NUMBER

1646

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DATE MAILED: 08/23/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

**Office Action Summary**

Application No.

09/421,971

Applicant(s)

GAGE ET AL.

Examiner

Joseph F Murphy

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 June 2001.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-60 is/are pending in the application.
- 4a) Of the above claim(s) 23-51 and 55-60 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-22 and 52-54 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4,5.

- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Election/Restrictions*

Applicant's election with traverse of Group I, claims 1-22 and 52-54 in Paper No. 7, 6/16/2001 is acknowledged. The traversal is on the grounds that: i) the inventions are not distinct and iii) no justification has been provided to restrict the claims into such an unreasonable number of groups. This is not found persuasive for the following reasons.

Applicant's attention is directed to MPEP 808.02 which states that "Where the related inventions as claimed are shown to be distinct under the criteria of MPEP 806.05 (c-i), the examiner, in order to establish reasons for insisting upon restriction, must show by appropriate explanation one of the following: (A) Separate classification thereof; (B) A separate status in the art when they are classifiable together; (C) A different field of search." As set forth in the Restriction requirement, the separate classification established for each Group demonstrates that each distinct Group has attained recognition in the art as a separate subject for inventive effort, and also a separate field of search. Thus, the Restriction requirement is proper.

Response to argument ii): Applicant argues that no justification has been provided to restrict the claims into such an unreasonable number of groups. As discussed above, the separate classification established for each Group demonstrates that each distinct Group requires a separate field of search, and a search of one Group would not reveal art on the other Groups, thus imposing a burden on the Examiner.

The requirement is still deemed proper and is therefore made FINAL. Claims 23-51, 55-60 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b).

***Claim Rejections - 35 USC § 112 first paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-22 and 52-54 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a chimeric protein comprising two functional units each comprising the dimerization domain of a steroid/thyroid hormone nuclear receptor superfamily with an optional linker wherein the receptor is an ecdysone receptor, a Usp receptor or a retinoid X receptor, does not reasonably provide enablement for a chimeric protein comprising two functional units each comprising the dimerization domain of a steroid/thyroid hormone nuclear receptor superfamily with an optional linker, where in the receptor is any other steroid/thyroid hormone nuclear receptor linker interposed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claim 1 is overly broad in the recitation of "steroid/thyroid hormone nuclear receptor superfamily" since the Specification provides insufficient guidance as to which of the myriad of fusion polypeptides encompassed by the claim will retain the functional characteristics such that it can be used as a non-mammalian based transcription regulating system (page 4, lines 11-18) which would require that it respond to application of hormone. In the specification (page 13, lines 18-30), Applicants disclose that members of the steroid/thyroid hormone superfamily of receptors include GR, MR, ER, PR, AR Vitamin D3 receptor and the like, without disclosing any actual or prophetic examples on expected performance parameters of any of the possible

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chimeric proteins comprising domains of these receptors. The results of making chimeric proteins comprising regions from these receptors are unpredictable. For instance, in the EMSA presented in Figure 2A, the E0U construct clearly shows no response to the application of mur A, while the E0R construct has a seven-fold increase in binding. Further, in the luciferase expression assay presented in Figure 3 the U0E, and E0U constructs also showed little response to mur A, while the E0R construct had a sixteen fold response. There is insufficient guidance provided in the specification as to how one of ordinary skill in the art would generate a chimeric protein comprising two functional units each comprising the dimerization domain of a steroid/thyroid hormone nuclear receptor superfamily with an optional linker other than those exemplified in the specification, i.e. comprising domains of the ecdysone, Usp or RXR receptor. See *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404. The test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue. The factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue" include, but are not limited to: (1) the breadth of the claims; (2) the nature of the invention; (3) the state of the prior art; (4) the level of one of ordinary skill; (5) the level of predictability in the art; (6) the amount of direction provided by the inventor; (7) the existence of working examples; and (8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. Given the breadth of claims 1-22 and 52-54 in light of the predictability of the art as determined by the number of working examples, the level of skill of the artisan, and the guidance provided in the instant

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specification and the prior art of record, it would require undue experimentation for one of ordinary skill in the art to make and use the claimed invention.

*Conclusion*

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Patent No. 5,599,904 Evans et al. Feb. 4, 1997.

U.S. Patent No. 4,981,784 Evans et al. Jan. 1, 1991.

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*Advisory Information*

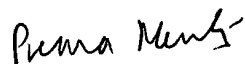
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph F. Murphy whose telephone number is 703-305-7245. The examiner can normally be reached on M-F 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 703-308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Joseph F. Murphy, Ph. D.  
Patent Examiner  
Art Unit 1646  
August 21, 2001

  
PREMA MERTZ  
PRIMARY EXAMINER